

IDS Form PTO/SB/08: Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known

| | |
|------------------------|-------------------|
| Application Number | 10/561,345 |
| Filing Date | December 20, 2005 |
| First Named Inventor | Udo KRUPKA |
| Art Unit | To be assigned |
| Examiner Name | To be assigned |
| Attorney Docket Number | 05552.1463-00 |

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS

| Examiner Initials | Cite No. ¹ | Document Number Number-Kind Code ² (if known) | Issue or Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|-------------------|-----------------------|---|---|---|---|
| | | | | | |

ALL REFERENCES

Note: Copies of the U.S. Patent Documents are not Required in IDS filed after October 21, 2004

FOREIGN PATENT DOCUMENTS

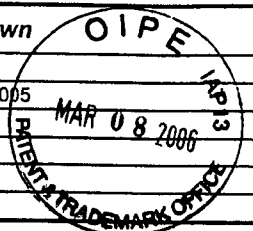
| Examiner Initials | Cite No. ¹ | Foreign Patent Document Country Code ³ Number ⁴ Kind Code ⁵ (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | Translation ⁶ |
|-------------------|-----------------------|--|--------------------------------|---|---|--------------------------|
| | | WO 02/079217 | 10-10-2002 | P. COLEMAN et al. | | |

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS); title of the article (when appropriate); title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | Translation ⁶ |
|-------------------|-----------------------|--|--------------------------|
| | | W. M. LEE, "Hepatitis B Virus Infection," <i>N. Engl. J. Med.</i> 337: 1733-1745 (1997). | |
| | | P. TIOLLAIS et al., "The hepatitis B virus," <i>Nature</i> , 317: 489-495 (1985). | |
| | | W. H. GERLICH et al., "Functions of Hepatitis B Virus Proteins and Virus Assembly," <i>Viral Hepatitis and Liver Disease</i> , 121-134 (1991). | |
| | | H. E. BLUM, "Variants of Hepatitis B, C and D Viruses: Molecular Biology and Clinical Significance," <i>Digestion</i> 56: 85-95 (1995). | |
| | | H. OKAMOTO et al., "Genomic Heterogeneity of Hepatitis B Virus in a 54-Year-Old Woman who Contracted the Infection through Materno-Fetal Transmission," <i>Jpn. J. Exp. Med.</i> 57: 231-236 (1987). | |
| | | W. CARMAN et al., "Viral genetic variation: hepatitis B virus as a clinical example," <i>Lancet</i> 341:349-353 (1993). | |
| | | A.M. COUROUCE Ed., Karger AG, Basel, Switzerland, <i>Bibliotheca Haematologica</i> 42: Table of Contents, pp. 1-19, (1976). | |
| | | H. NORDER et al., "Molecular basis of hepatitis B virus serotype variations within the four major subtypes," <i>J. Gen. Virol.</i> 73: 3141-3145 (1992). | |
| | | H. NORDER et al., "Complete Genomes, Phylogenetic Relatedness, and Structural Proteins of Six Strains of the Hepatitis B Virus, Four of Which Represent Two New Genotypes," <i>Virology</i> 198: 489-503 (1994). | |
| | | N. A. TERRAULT et al., "Incidence and Clinical Consequences of Surface and Polymerase Gene Mutations in Liver Transplant Recipients on Hepatitis B Immunoglobulin," <i>Hepatology</i> 28:555-561 (1998). | |
| | | H. L. TILLMANN et al., "Mutational Pattern of Hepatitis B Virus on Sequential Therapy With Famciclovir and Lamivudine in Patients With Hepatitis B Virus Reinfection Occurring Under HBIG Immunoglobulin After Liver Transplantation," <i>Hepatology</i> 30: 244-256 (1999). | |
| | | C. M. HUNT et al., "Clinical Relevance of Hepatitis B Viral Mutations," <i>Hepatology</i> 31: 1037-1044 (2000). | |
| | | M. P. COOREMAN et al., "Vaccine- and Hepatitis B Immune Globulin-Induced Escape Mutations of Hepatitis B Virus Surface Antigen," <i>J. Biomed. Science</i> 8:237-247 (2001). | |
| | | D. L. PETERSON et al., "Antigenic Structure of Hepatitis B Surface Antigen: Identification of the "d" Subtype Determinant by Chemical Modification and Use of Monoclonal Antibodies," <i>J. Immunol.</i> 132:920-927 (1984). | |
| | | W. JILG, "Novel hepatitis B vaccines," <i>Vaccine</i> 16: S65-S68 (1998). | |
| | | W. F. CARMAN et al., "Hepatitis B Virus Envelope Variation After Transplantation With and Without Hepatitis B Immune Globulin Prophylaxis," <i>Hepatology</i> 24:489-493 (1996). | |
| | | R. MÜLLER et al., "Liver transplantation in HBs antigen (HBsAg) carriers," <i>J. Hepatol.</i> 13:90-96 (1991). | |
| | | D. SAMUEL et al., "Liver transplantation in European Patients with the Hepatitis B Surface Antigen," <i>N. Engl. J. Med.</i> 329:1842-1847 (1993). | |
| | | A. BRIND et al., "Evidence for selection of hepatitis B mutants after liver transplantation through peripheral blood mononuclear cell infection," <i>J. Hepatol.</i> 26:228-235 (1997). | |

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /Z.L./

| | | | |
|---|---|--------------------------|-------------------|
| IDS Form PTO/SB/08: Substitute for form 1449A/PTO | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | Application Number | 10/561,345 |
| | | Filing Date | December 20, 2005 |
| | | First Named Inventor | Udo KRUPKA |
| | | Art Unit | To be assigned |
| | | Examiner Name | To be assigned |
| | | Attorney Docket Number | 05552.1463-00 |
| Sheet | 2 | of | 2 |



| NON PATENT LITERATURE DOCUMENTS | | |
|---------------------------------|--|--|
| | L. FISCHER et al., "Hepatitis B Virus Variants Associated With Clinically Severe Recurrence After Liver Transplantation," <i>Transplantation Proceedings</i> 31: 492-493 (1999). | |
| | M. G. GHANY et al., "Hepatitis B Virus S Mutants in Liver Transplant Recipients Who Were Reinfected Despite Hepatitis B Immune Globulin Prophylaxis," <i>Hepatology</i> 27:213-222 (1998). | |
| | U. PROTZER-KNOLLE et al., "Hepatitis B Virus With Antigenically Altered Hepatitis B Surface Antigen Is Selected by High-Dose Hepatitis B Immune Globulin After Liver Transplantation," <i>Hepatology</i> 27: 254-263 (1998). | |
| | W. F. CARMAN et al., "Genetic Variation in Hepatitis B Virus," <i>Gastroenterology</i> 102: 711-719 (1992). | |
| | W. F. CARMAN, "The clinical significance of surface antigen variants of hepatitis B Virus," <i>J. Viral Hepatol.</i> 4(suppl 1): 11-20 (1997). | |
| | P. D. SWENSON et al., "Determination of HBsAg subtypes in different high risk populations using monoclonal antibodies," <i>J. Virol. Meth.</i> 33: 27-28 (1991). | |
| | L. BLITZ et al., "Antigenic Diversity of hepatitis B Virus Strains of Genotype F in Amerindians and Other Population Groups from Venezuela," <i>J. Clin. Microbiol.</i> 36: 648-651 (1998). | |
| | P. G. ASHTON-RICK ARDT et al., "Mutations That Change the Immunological Subtype of Hepatitis B Virus Surface Antigen and Distinguish Between Antigenic and Immunogenic Determination," <i>J. Med. Virol.</i> 29: 204-214 (1989). | |
| | K. I. OHBA et al., "Relationships between serotypes and genotypes of hepatitis B virus: genetic classification of HBV by use of surface genes," <i>Virus. Res.</i> 39: 25-34 (1995). | |
| | W. F. CARMAN et al., "Fulminant reactivation of hepatitis B due to envelope protein mutant that escaped detection by monoclonal HBsAg ELISA," <i>Lancet</i> 345: 1406-1407 (1995). | |
| | H. OKAMOTO et al., "Mutations within the S Gene of Hepatitis B Virus Transmitted from Mothers to Babies Immunized with Hepatitis B Immune Globulin and Vaccine," <i>Pediatr. Res.</i> 32: 264-268 (1992). | |
| | Y. Y. ZHANG et al., "Increasing Heterogeneity of the 'a' Determinant of HBsAg Found in the Presumed Late Phase of Chronic Hepatitis B Virus Infection," <i>J. Infect. Dis.</i> 28: 9-15 (1996). | |
| | A. J. ZUCKERMANN et al., "Mutations in S region of hepatitis B virus," <i>Lancet</i> 343: 737-738 (1994). | |
| | T. F. SMITH et al., "Comparison of Biosequences," <i>Adv. Appl. Mathem.</i> 2: 482-489 (1981). | |
| | R. M. SCHWARTZ et al., M. D. Dayhoff, Ed., "Matrices for Detecting Distant relationships," <i>Atlas of Protein Sequence and Structure Suppl</i> 3, pp. 353-358, Nat. Biomed. Res. Found., Washington D. C. (1978). | |
| | M. GRIBSKOV et al., "Sigma factors from <i>E. coli</i> , <i>B. subtilis</i> , phage SP01, and phage T4 are homologous proteins," <i>Nucleic. Acids Research</i> 14: 6745-6763 (1986). | |
| | J. SAMBROOK et al., <i>Molecular Cloning, Volume I</i> , pp. xi-xxxviii, Cold Spring Harbor Lab. Press (1989). | |
| | F. M. AUSUBEL et al., <i>Current Protocols in Molecular Biology</i> , pp. iii-xviii, Greene Publishing (1992). | |
| | G. KÖHLER et al., "Continuous cultures of fused cells secreting antibody of predefined specificity," <i>Nature</i> 256: 495-497 (1975). | |
| | L. T. MIMMS et al., "Discrimination of Hepatitis B Virus (HBV) Subtypes Using Monoclonal Antibodies to the PreS1 and PreS2 Domains of the Viral Envelope," <i>Virology</i> 176: 604-619 (1990). | |

| | | | |
|--------------------|-------------------|-----------------|------------|
| Examiner Signature | /Zachariah Lucas/ | Date Considered | 10/02/2008 |
|--------------------|-------------------|-----------------|------------|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /Z.L./